

Durability of renal artery stents in patients with transrenal abdominal aortic endografts

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Objective: The management of renal artery stenosis in patients with abdominal aortic aneurysms continues to be complex and technically challenging despite advances in endovascular therapy. There is growing concern about the durability of renal artery stents in the setting of transrenal abdominal aortic endografts. This study reports a single-center experience of renal artery stenting with transrenal abdominal aortic endografts for patients with renal artery stenosis.

Methods: All patients undergoing endovascular abdominal aortic aneurysm repair preceded or followed by renal artery stent placement between January 1999 and December 2005 were retrospectively reviewed from a prospectively gathered endovascular database. Patients were surveyed after renal stent procedures with multidetector computed tomography angiography or duplex sonography. The surveillance data were analyzed for primary patency of the renal artery stent at 6 months, incidence of complications, need for secondary interventions, and changes in creatinine clearance (CrCl).

Results: Sixty-two renal artery stents were placed in 56 patients (44 men, 12 women) with a mean age of 77.3 years (range, 61 to 94 years). Forty-one were placed before the endograft procedure, eight were placed during the endograft procedure, and 13 were placed postoperatively. There were no major or minor complications related to the renal artery stent procedures. Transrenal aortic endografts were used in 44 of the 56 patients, and 12 had devices with infrarenal fixation. The mean follow-up was 18.5 months (range, 1 to 73 months). The 6-month primary patency, which could be evaluated for 51 renal artery stents, was 97.4% (37/38) in patients with transrenal fixation and 84.6% (11/13) in patients with infrarenal fixation. The overall rate of in-stent restenosis was 8.5% (4/47) in the transrenal fixation group and 20.0% (3/15) in the infrarenal fixation group. The overall occlusion rate was 2.1% (1/47) in the transrenal fixation group and 0% (0/15) in infrarenal fixation group. Five (83.3%) of six patients underwent successful treatment of in-stent restenosis with placement of a new stent in all five cases. CrCl decreased in the total group by 4.2 ± 11.8 mL/min, by 4.7 ± 12.0 mL/min in patients with transrenal fixation, and by 2.2 ± 11.0 mL/min in patients with infrarenal fixation.

Conclusion: The presence of a transrenal aortic endograft did not affect the outcome of the renal artery revascularization procedure in this cohort. Renal artery stenting in the presence of transrenal abdominal aortic endografts appears to be a safe procedure without adverse effect on renal artery stent patency or renal function. (J Vasc Surg 2007;45:915-21.)

Endovascular repair of abdominal aortic aneurysms (AAAs) has evolved tremendously since the first aortic endograft was implanted more than a decade ago.¹ Advances in material and device manufacturing, together with improvements in surgical technique, have expanded the population of patients eligible for endovascular abdominal aortic aneurysm repair (EVAR). The development of stent grafts with an uncovered proximal landing zone allows transrenal fixation across the renal arteries, thereby opening endovascular doors for patients with short infrarenal necks. Studies have shown promising results in these patients, claiming adequate proximal fixation, no increased risk of type I endoleaks, and no evidence of renal sequelae in short-term follow-up.²⁻⁵ As the population of patients

whose AAAs are now amenable to endovascular repair grows, new morphologic criteria continue to be reassessed to determine the feasibility of EVAR in those aneurysms.

Patients with AAAs often have concomitant atherosclerotic disease of their renal and iliac arteries. EVAR in a patient with atherosclerotic, tortuous iliac vessels is associated with an increased complexity of the repair.⁶⁻⁸ To our knowledge, however, how renal artery stenosis affects endovascular repair has not been addressed in the literature.

In the past, patients with renal artery stenoses were offered renal artery bypass or endarterectomy at the time of their open AAA repair. Now, percutaneous treatment of renal artery stenosis with angioplasty and stents is considered safe and effective.⁹⁻¹⁴ To decrease the risk of restenosis of the renal artery, the stent needs to be placed 1 to 2 mm into the aortic lumen to cover the renal ostium.¹² Because of the position of the renal artery stent in the aortic lumen, one can postulate that difficulties can occur with transrenal placement of endovascular stent grafts.

In addition to interfering with the placement of a transrenal endograft, the presence of a renal artery stent in the aorta adjacent to a transrenal endograft could potentially interfere with the integrity of the renal artery stent and

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increase the risk of postoperative renal complications. The purpose of this study was to determine the effects of transrenal placement of endografts in patients with renal artery stents.

METHODS

A retrospective review of a prospectively gathered endovascular database was performed for all patients undergoing EVAR at our institution between January 1999 and December 2005. Patients gave written informed consent and were treated in accordance with the approval of the Mount Sinai Medical Center Institutional Review Board. All patients undergoing EVAR preceded or followed by renal artery stent placement during this period were identified.

All patients underwent preoperative contrast-enhanced computed tomography (CT) and arteriography to evaluate AAA anatomy. Preoperative baseline serum creatinine (Cr) levels were also obtained. Patients with chronic renal insufficiency (Cr >1.5 mg/dL) are hydrated with alkalized fluids for 2 to 4 hours before and after their CT angiography (CTA) or arteriography imaging study.

Patients selected for renal artery stenting demonstrated >70% renal artery stenosis on selective arteriography in the setting of clinical hypertension or renal insufficiency. During preoperative calibrated arteriography, asymptomatic patients with >90% stenosis underwent renal artery stent placement to protect against atheroembolic complications during EVAR. Although this practice will not protect patients from smaller segmental infarctions, it should prevent complete renal artery occlusion in this patient population.

Renal artery stents were placed intraoperatively in patients who had perceived coverage of the renal artery orifice by the aortic endograft or as salvage procedures in patients who had sustained embolic events. Renal artery stents were placed after EVAR in patients who had progressive disease that did not initially meet criteria preoperatively. Preoperative treatment, when indicated, was preferred because of the technical difficulties that may arise once a transrenal endograft is in place.

All patients underwent percutaneous femoral or brachial artery access under local anesthesia alone or combined with conscious sedation. Brachial artery access was chosen as the first-line access for patients who were treated after EVAR. Once the renal artery was cannulated, before angioplasty and stent deployment, 3000 U of heparin was given systemically.

Throughout the series, balloon-expandable stainless steel renal artery stents were used. Initially, the Corinthian 0.035-inch (Cordis/Johnson & Johnson, Warren, NJ) system was used, and later, the Genesis 0.014-inch (Cordis/Johnson and Johnson) system was used.

All patients underwent a completion renal angiogram that confirmed stent placement and resolution of the stenosis. If a residual narrowing remained after stent deployment, the stent was postdilated until an acceptable lumen was demonstrated.

All EVAR procedures were performed in the operating room under spinal anesthesia with portable C-arm fluoroscopy. Access to the arterial system was through a cutdown across one or both femoral arteries. Completion angiograms were obtained in all patients after deployment of the stent graft to confirm aneurysm exclusion and renal artery patency.

Follow-up for all patients undergoing EVAR consisted of an office visit with the operating surgeon as well as plain abdominal radiography and three-phase contrast-enhanced CTA at 1 month, 6 months, 12 months, and annually thereafter. Patients were surveyed after renal stent procedures with CTA and duplex sonography imaging along with measurements of serum creatinine. The surveillance data were analyzed for primary patency of the renal artery stent at 6 months, incidence of complications, need for secondary interventions, and changes in creatinine clearance (CrCl), which was estimated using the Cockcroft-Gault formula: $\text{CrCl} = (140 - \text{age}) \times \text{weight} / (\text{SCr} \times 72)$, which was adjusted for women by multiplying the result by 0.85.¹⁵ This formula was selected as a simple means of standardizing renal function by weight, gender, and age, although it is known to overestimate glomerular filtration rate.¹⁶

Statistical analysis was performed using SPSS 14.0 statistical software (SPSS Inc, Chicago, Ill) and GraphPad Prism (GraphPad Software, Inc, San Diego, Calif). Data were expressed as mean \pm standard deviation. Continuous variables were compared using the Student *t* test. Univariate analysis of categorical variables was performed with the Fisher exact test or χ^2 analysis when appropriate. Differences were considered significant at $P < .05$.

RESULTS

During the period reviewed, 924 EVARs were performed at our institution in which 56 patients (6.1%) had renal artery stents placed. This cohort was a mean age of 77.3 ± 7.3 years and included 44 men (78.6%) and 12 women (21.4%). Two patients had previously undergone nephrectomies for malignancy, and two patients had chronic unilateral renal artery occlusion.

Sixty-two renal artery stents were placed in these 56 patients, including 50 patients who had unilateral stent placement and six who had bilateral stent placement. The timing of stent placement included 41 stents (66.1%) inserted before the EVAR procedure, eight (12.9%) inserted during the EVAR procedure, and 13 (21.0%) placed after EVAR (Fig 1 and Fig 2). Asymptomatic high-grade renal artery stenoses were present in 11 of the 39 patients who underwent renal artery stenting before EVAR, and 28 had chronic renal insufficiency (Cr >1.5 mg/dL) along with some degree of hypertension. The six patients treated intraoperatively all had perceived flow-limiting coverage by the aortic endograft or atheroemboli. Four of the 11 patients treated after EVAR had uncontrolled hypertension, and seven had a combination of renal insufficiency and hypertension.

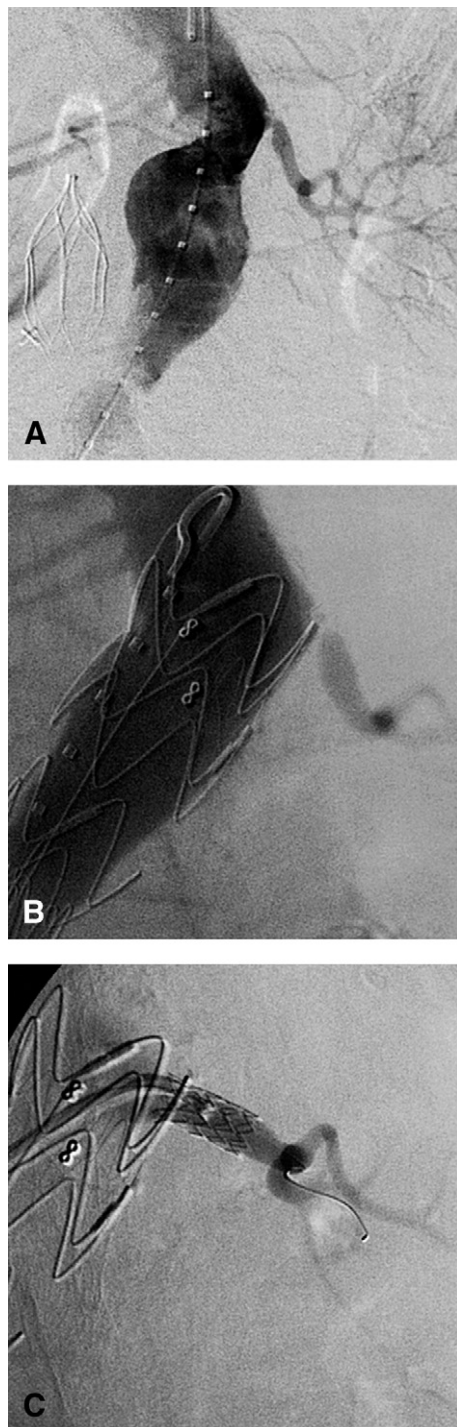


Fig 1. A, Preoperative angiogram demonstrates a 5.9-cm abdominal aortic aneurysm and <50% left renal artery stenosis. B, An angiogram obtained 18 months after endovascular aneurysm repair with a Talent aortouniiliac device demonstrates severe left renal artery stenosis. C, Completion angiogram demonstrates successful renal artery stenting through the transrenal struts of the Talent device.

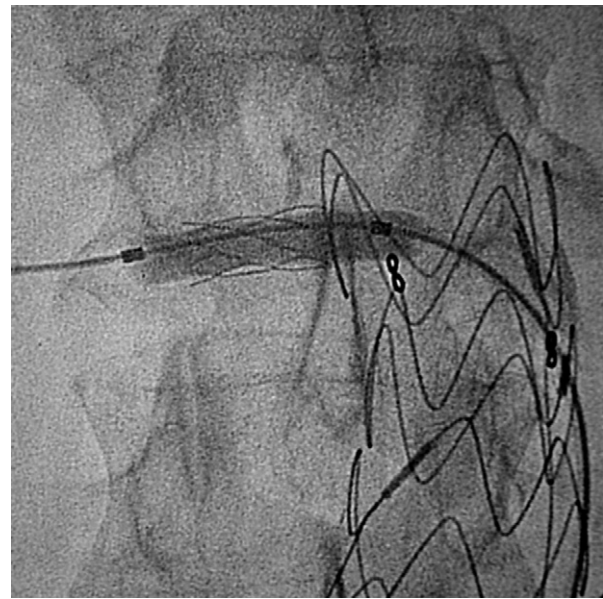


Fig 2. Balloon angioplasty of a renal artery stent through the transrenal struts of a Talent endograft.

There were no major or minor complications related to the renal artery stent procedures. Transrenal aortic endografts were placed in 44 (78.6%) of the 56 patients, and infrarenal fixation devices were used in 12 (21.4%). The 44 transrenal endografts included 37 Talent (Medtronic World Medical, Sunrise, Fla) devices, two Cordis (Cordis/Johnson and Johnson) devices, two Zenith (Cook, Bloomington, Ind) devices, and three homemade custom-made Parodi (Johnson & Johnson, Somerville, NJ)/Palmaz (Impra, C. R. Bard, Murray Hill, NJ) devices. The 12 devices with infrarenal fixation included seven Gore (W. L. Gore & Associates, Flagstaff, Ariz) devices and five Aneurx (Medtronic/AVE, Santa Rosa, Calif) devices. The configurations for these devices included 40 bifurcated devices, 12 aortouniiliac devices, and four aortoaortic tube devices.

The mean follow-up was 18.5 ± 18.6 months. Six-month primary patency, which could be evaluated for 51 renal artery stents, was 97.4% (37/38) in patients with transrenal fixation and 84.6% (11/13) in patients with infrarenal fixation. No statistically significant difference was noted in 6-month patency between the two groups ($P = .16$). All three stents that developed restenosis within 6 months were successfully treated with secondary angioplasty and stenting. The overall rate of in-stent restenosis for the 62 renal artery stents was 8.5% (4/47) in the transrenal fixation group and 20.0% (3/15) in the infrarenal fixation group. In-stent restenosis between the two groups was not statistically significant ($P = .35$). Six (85.7%) of seven patients underwent successful treatment of in-stent restenosis with placement of a new stent.

One of these patients initially underwent secondary angioplasty and stenting 7 months after his initial renal

Freedom from renal artery stent occlusion/in-stent restenosis

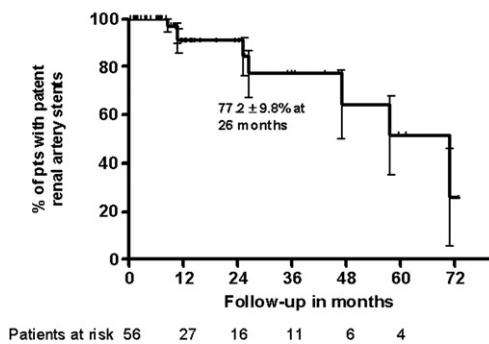


Fig 3. Survival curve demonstrates freedom from renal artery stent occlusion and in-stent restenosis in patients with renal artery stents and aortic endografts.

artery stenting, followed by renal artery cryoplasty 12 months later, and finally, angioplasty and stenting 6 months after that. The patient who was unable to undergo successful treatment of his in-stent restenosis had a chronically occluded left renal artery and underwent successful stenting of his right renal artery before EVAR. He was readmitted 8 months after his EVAR with acute renal failure at which time an attempt was made to recanalize his right renal artery. This was unsuccessful. The patient refused dialysis and later died.

The overall occlusion rate was 2.1% (1/47) in the transrenal fixation group and 0% (0/15) in the infrarenal fixation group ($P = 1.0$). Survival-curve analysis estimated that approximately 80% of patients with renal artery stents who underwent EVAR will be free from stent occlusion or in-stent restenosis at 24 months (Fig 3).

Twenty-one patients (37.5%) had baseline renal insufficiency (serum creatinine >1.5 mg/dL), including 17 (38.6%) of 44 patients in the transrenal fixation group and four (33.3%) of 12 in the infrarenal fixation group. Baseline CrCl was not significantly different between those patients who underwent EVAR with transrenal fixation devices and those who had infrarenal fixation devices (54.5 ± 27.0 mL/min vs 49.1 ± 18.3 mL/min, $P = .52$). CrCl decreased in the overall group by 4.2 ± 11.8 mL/min during the follow-up period, from 53.3 ± 25.3 mL/min to 49.2 ± 23.6 mL/min. CrCl decreased by 4.7 ± 12.0 mL/min in patients with transrenal fixation devices and by 2.2 ± 11.0 mL/min in patients with infrarenal fixation devices. There was no statistically significant difference in change in CrCl between the two groups ($P = .53$; Fig 4).

In seven patients (12.5%), the decrease in CrCl was $>30\%$ of their baseline, including five (11.4%) of 44 patients in the transrenal fixation group and two (16.7%) of 12 in the infrarenal fixation group. Five of these patients had baseline renal insufficiency. Only one went on to require dialysis, which as aforementioned, the patient refused.

Changes in CrCl in patients with infrarenal vs. transrenal fixation devices

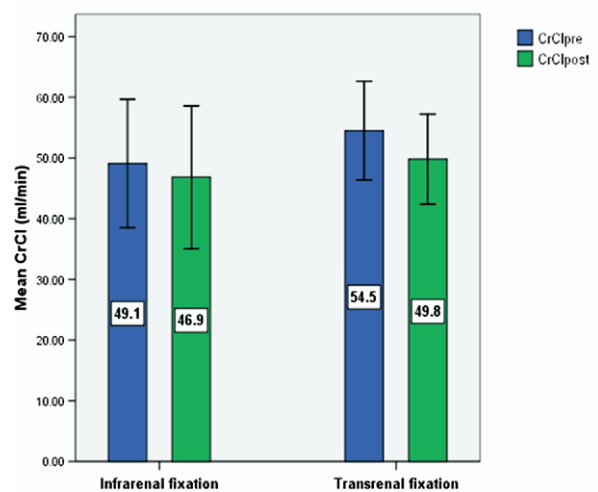


Fig 4. Changes in creatine clearance (CrCl) in patients with renal artery stents and infrarenal vs transrenal aortic endografts during the follow-up period. Data are presented as mean \pm standard deviation.

DISCUSSION

Ever since being first described more than 15 years ago, EVAR has emerged as an excellent alternative to open repair of AAAs.¹ Despite the popularity of the procedure, only a certain percentage of patients with AAAs are candidates for this form of therapy. Anatomic limitations, such as an angulated or short proximal infrarenal implantation site, can place a patient at risk for postoperative complications that include endoleak, aneurysm sac enlargement, and even aneurysm rupture.

Suprarenal fixation has been proposed as an effective solution to overcome the anatomic constraints of certain AAAs, particularly with respect to the proximal seal zone.² Suprarenal fixation has been theorized to increase patient eligibility and prevent late device migration and endoleak.¹⁷ Some studies have suggested improved outcomes with suprarenal fixation by decreasing the incidence of late endoleaks.¹⁸ Many authors have reported excellent immediate and intermediate results with these devices. There still exists a sense of concern about the effects on the renal arteries and renal parenchyma in the setting of bare metal struts crossing the origins of the renal arteries.¹⁹

Most studies that have analyzed the effect of suprarenal fixation compared with infrarenal fixation on renal function have shown no differences between the two groups.^{2,4,5} Furthermore, one study has shown that the impact of a suprarenal endograft on renal function is not dissimilar from the impact of a standard open repair on renal function.²⁰ One of the comparative studies demonstrated a significant increase in the incidence of postoperative renal impairment in the suprarenal fixation group compared with the infrarenal fixation group.²¹ The mechanism for these observations is unclear.

Previous studies have reported punctate perfusion defects observed in the renal parenchyma after EVAR that would suggest an atheroembolic potential of the EVAR procedure.²² Another potential risk would be the exacerbation of an atherosclerotic narrowing in the presence of suprarenal fixation, which has been suggested by previous studies.

Lobato et al¹⁹ reported a patient with a suprarenal aortic endograft and 60% renal artery stenosis which progressed to 99% at 4 months after EVAR. Bove et al³ also observed the progression of an ostial renal artery stenosis in the setting of suprarenal fixation.

Lau et al²³ reported a single-center experience in the use of aortic endografts with suprarenal fixation and compared those results with the same center's experience with infrarenal devices. No difference was noted in renal function between the two groups at 12 months in their study, but two renal artery occlusions were observed in the suprarenal fixation group and none in the infrarenal fixation group. It was mentioned that these two patients had previously observed ostial atherosclerotic narrowings >50% that were not revascularized before EVAR. These authors recommended caution when suprarenal fixation is considered in patients with pre-existing atherosclerotic renal artery stenosis.

Recent studies have attempted to quantitate the amount of coverage of the renal artery ostia created by transrenal fixation of an aortic endograft. England et al²⁴ used three-dimensional CT reconstruction software to create virtual intravascular endoscopies of 55 patients who underwent EVAR with Talent aortic endografts. In their study, only 40% of patients had a stent strut cross a renal artery unilaterally, and 9% had stent struts crossing both renal artery ostia. The incidence of renal artery coverage did not affect renal function.²⁴

Another study by Sun et al²⁵ demonstrated 90% of renal artery ostia to be involved by the suprarenal struts of the Zenith device. Most of the cases presented in their series were repaired using the Talent aortic endograft, which has a unique design compared with other aortic devices with suprarenal fixation. One specific characteristic is the lack of fixation hooks compared with the Zenith device. Another characteristic is the relative wide spacing and fewer numbers of suprarenal struts compared with the Zenith device. The Zenith device is not used routinely at our institution, and their series has limited relevance for patients treated with that specific device design.

Recently, there has been great interest in the applicability of EVAR for patients with juxtarenal or pararenal aneurysms. Feasibility studies have been published on the use of fenestrated Zenith devices for the treatment of these patients.²⁶ In these cases, the fabric of the endovascular device is implanted higher than the renal artery ostia, with scallops or fenestrations created to allow perfusion of the kidneys. These openings are secured in place with transluminally placed renal artery stents at the time of the aortic repair.

Although these studies have demonstrated feasibility, there appears to be significant renal effects with these devices encroaching fabric on the renal artery ostia, in some instances circumferentially. In a series of 72 patients, Haddad et al²⁷ reported an overall incidence of significant renal function deterioration of 33%. The major risk factor for this outcome was pre-existing renal dysfunction with an estimated glomerular filtration rate of <60 mL/min. Adverse renal events in this cohort included renal artery stenosis, renal artery occlusion, and renal failure requiring dialysis.

CONCLUSIONS

The early results of the use of renal artery stents in fenestrated aortic endografts are discouraging and should be viewed with caution. The series presented here did not have the same incidence of adverse outcomes. One explanation may be the use of different endografts. In particular, a large number of patient in this series were treated with Talent endografts, which are not currently approved for use by the United States Food and Drug Administration. Another may be the intrinsic difference between a device with a suprarenal bare stent and one with suprarenal fabric and renal fenestrations.

To our knowledge, this is the first study to review a series of renal artery stents placed for atherosclerotic ostial stenoses in the presence of a suprarenal aortic endograft. These results offer preliminary evidence to support the use of this technology without risks of significant adverse events. The incidence of adverse stent associated events including in-stent stenosis and stent occlusion were similar to previously published series on renal artery ostial stenting for atherosclerotic lesions.

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AUTHOR CONTRIBUTIONS

Conception and design: DB, RL, MM

Analysis and interpretation: DB, RL, TJ

Data collection: DB, JW

Writing the article: DB, RL, TJ

Critical revision of the article: DB, RL, TJ, JW, MM

Final approval of the article: DB, RL, TJ, JW, MM

Statistical analysis: DB, RL

Obtained funding: MM

Overall responsibility: DB

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DISCUSSION

Dr Michael J. Costanza (Syracuse, NY). Dr Baril and the Mount Sinai group have addressed an important problem that virtually every vascular specialist has faced: how to manage renal artery stenosis in a patient awaiting or undergoing an endovascular abdominal aortic aneurysm repair. The decision-making on these patients can be challenging for several reasons, which you have clearly outlined in your paper.

Your results indicate that renal artery stenting before, during and after EVAR is feasible even with transrenal fixation devices. I am convinced that we can perform renal artery stenting in these patients, but I'd like you to tell us if we should be doing this.

My first question is about the natural history of renal artery stenosis and EVAR. Have you looked at your center's over 900 endovascular aneurysm repairs to identify and track patients with renal artery stenosis who are managed medically after their EVAR? This information would be helpful in determining how aggressively we should look for and treat renal artery stenosis in these patients.

Secondly, did renal artery stenting confer any clinical benefits for these treated patients? Was their blood pressure controlled with fewer medications? Did they have a slower rate of renal decline?

Although you did not detect a change in creatinine clearance in your series, creatinine can be an insensitive indicator for renal function. Also, only a third of your patients had renal insufficiency, which implies that the majority of patients either were hypertensive or asymptomatic.

And finally, detailed CT scans and CT angiograms have made preoperative angiography unnecessary for many patients awaiting EVAR. How would you suggest that these patients be managed with respect to evaluating them for renal artery stenosis? Is it reasonable to identify and treat renal artery stenosis at the time of an endovascular aneurysm repair or should they be treated in a staged fashion?

Dr Donald T. Baril. In reference to your first question, as to whether we have looked at the natural history of renal stenosis in these patients, we have previously, and observed that essentially patients with renal artery stenosis with a transrenal aortic endograft tend to have the same natural course as if the graft is not there. They have progression of the disease, but not at a rate higher than would be expected without the presence of the endograft.

That being said, the patients that we choose to place renal artery stents in preoperatively are those that have high-grade

stenosis greater than 90%. Even in asymptomatic patients we had a concern of atheroembolic events at the time of aortic endograft deployment.

Additionally, patients with 70% or greater stenosis in the setting of clinical hypertension or renal insufficiency have also been stented.

In reference to your second question of the clinical benefits, that was not specifically examined in this series. There are anecdotal reports from our own institution that some patients have been weaned off antihypertensives whereas others have continued to require equal or greater doses. However, the patients with renal insufficiency who underwent renal artery stenting have basically maintained their renal function.

Finally, in reference to your last question, our institution has continued to do preoperative angiography for a number of different reasons. One is the belief that this is the best means of measuring aneurysm and aortic length. Additionally, a large number of our cases are referred to our tertiary referral center and require adjuvant therapy, whether it be a renal artery stent or hypogastric embolization, before endograft deployment.

That being said, if a renal artery lesion is found on CT angiography, the next step would be to perform a renal artery duplex to determine the clinical significance of the stenosis. Based on the results of the duplex, we would recommend a staged procedure to minimize operative time as well as contrast load in what is often a renal insufficient population.

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